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## **Women's reasons for participation in a clinical trial for menstrual pain: a qualitative study**

Blödt, Susanne ; Witt, Claudia M ; Holmberg, Christine

**Abstract:** **OBJECTIVES:** The aim of the study was to explore women's motivations for participating in a clinical trial and to evaluate how financial compensation impacts women's explanations for participation. **DESIGN, SETTING AND PARTICIPANTS:** Semistructured interviews were conducted face to face or by telephone with 25 of 220 women who participated in a pragmatic randomised trial for app-administered self-care acupuncture for dysmenorrhoea (AKUD). Of these 25 women, 10 had entered AKUD knowing they would receive a financial compensation of €30. A purposive sampling strategy was used. **RESULTS:** Women had a long history of seeking help and were unsatisfied with the options available, namely painkillers and oral contraceptives. While interviewees were open to painkillers, they were uneasy about taking them on a monthly basis. The AKUD trial offered the possibility to find an alternative solution. A second reason for participation was the desire to add a new treatment to routine medical care, for which the interviewees considered randomised trials a prerequisite. The financial incentive was a subsidiary motivation in the interviewees' narratives. **CONCLUSIONS:** Our results contribute to the ongoing discussion of the impact of financial compensation on research participants' assessment of risk. The interviewed women considered all research participants able to make their own choices regarding trial participation, even in the face of financial compensation or payment of study participants. Furthermore, the importance of clinical trials providing new treatments that could change medical practice might be an overlooked reason for trial participation and could be used in future recruitment strategies.

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# BMJ Open Women's reasons for participation in a clinical trial for menstrual pain: a qualitative study

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## ABSTRACT

**Objectives:** The aim of the study was to explore women's motivations for participating in a clinical trial and to evaluate how financial compensation impacts women's explanations for participation.

**Design, setting and participants:** Semistructured interviews were conducted face to face or by telephone with 25 of 220 women who participated in a pragmatic randomised trial for app-administered self-care acupuncture for dysmenorrhoea (AKUD). Of these 25 women, 10 had entered AKUD knowing they would receive a financial compensation of €30. A purposive sampling strategy was used.

**Results:** Women had a long history of seeking help and were unsatisfied with the options available, namely painkillers and oral contraceptives. While interviewees were open to painkillers, they were uneasy about taking them on a monthly basis. The AKUD trial offered the possibility to find an alternative solution. A second reason for participation was the desire to add a new treatment to routine medical care, for which the interviewees considered randomised trials a prerequisite. The financial incentive was a subsidiary motivation in the interviewees' narratives.

**Conclusions:** Our results contribute to the ongoing discussion of the impact of financial compensation on research participants' assessment of risk. The interviewed women considered all research participants able to make their own choices regarding trial participation, even in the face of financial compensation or payment of study participants. Furthermore, the importance of clinical trials providing new treatments that could change medical practice might be an overlooked reason for trial participation and could be used in future recruitment strategies.

## INTRODUCTION

Randomised clinical trials are seen as the gold standard in clinical research, yet their success depends on the willingness of people to volunteer. Poor recruitment for clinical studies impacts statistical power, internal and external validity and can cause financial and practical restrictions.<sup>1</sup> Recruitment problems are a common obstacle in clinical studies<sup>2–3</sup>

## Strengths and limitations of this study

- The special setting of our study that included women who had entered the clinical trial both knowing and not knowing that they would receive a financial compensation of €30 allowed us to focus on the role of financial compensation in the decision-making processes of women when deciding on trial participation.
- The study contributes to understanding how altruistic and personal reasons influence trial participation.
- Sampling bias might have occurred because our sample was predominantly highly educated, including many with a medical background.
- Generalisability of our results is confined to women unsatisfied with the solutions for menstrual pain offered within the health system.

and numerous strategies have been identified to improve recruitment, including programmes to increase potential participants' awareness of a health problem and its possible impact on them,<sup>4</sup> making telephone contact with potential participants and using opt-out rather than opt-in procedures.<sup>5</sup> Campbell *et al*<sup>6</sup> found that certain factors proved successful in recruitment, including having a dedicated trial manager, it being a cancer drug trial and having interventions only available within the trial. Thus, both trial characteristics and communication strategies with potential participants are of importance for recruitment.

The payment of research participants has also been shown to increase participation.<sup>7</sup> Such a strategy is controversial, however, as it may influence individuals' informed decision-making.<sup>5</sup> In particular, it is argued that payment may unduly influence socio-economically disadvantaged populations<sup>8</sup> and could jeopardise informed consent and participants' autonomous ability to properly assess risks and benefits.<sup>9–10</sup> Indeed, studies have shown that higher compensation increases willingness to participate and that

participants will assume higher risks when compensation is high.<sup>11 12</sup> It has been argued that whether it is ethical to pay research participants depends on the purpose of payment.<sup>8</sup> Ethical concerns do not generally affect studies with minimal risk of harm<sup>13</sup> or those that reimburse only for time and travel expenses,<sup>9</sup> but do arise when payments exceed a certain threshold and/or compensate for potential risk.

There exists a range of studies from the USA investigating the participation of healthy volunteers in phase 1 clinical trials.<sup>14–17</sup> Such trials investigate a treatment in humans for the first time to test the safety of a drug, and are thus precarious in several ways and pose particular ethical problems. For instance, the risk of participation in trials is unknown and they require healthy volunteers who will be very closely monitored and must invest a large amount of their time. For this, participants receive payment. Often, participants in phase 1 studies include people in precarious financial situations, who may be serial study participants.<sup>14 15 18</sup>

To the best of our knowledge, only one study until now has looked at research participants' perspectives on financial compensation in phase 3 clinical trials—which assess the effectiveness of a new intervention and its value in clinical practice—with mixed results.<sup>19</sup> Some of the unpaid participants argued that compensation is a valid recognition of participants; others clearly disagreed with the idea of paid participation, arguing that it is a moral duty. Altruism and the wish to benefit others and oneself have been identified as major reasons for participating in phase 3 clinical trials,<sup>20–24</sup> though given the evidence that communication strategies and trial characteristics might also be important motivations, the question arises of what altruism, moral duty and benefit to others actually imply. Indeed, it remains unclear how financial compensation actually influences participants' willingness to enroll in research and what other factors also play a role.

### **Trial for acupuncture against menstrual pain (AKUD)**

The randomised pragmatic trial AKUD<sup>25</sup> was set up to assess the effectiveness of self-acupuncture supported by a smartphone app (intervention), compared to usual care (control group), for 220 women with menstrual pain (trial registered at [clinicaltrials.gov](http://clinicaltrials.gov) under NCT01582724). All women received the AKUD app, which provided questionnaires, diaries and, for the women in the intervention group, guidance on self-acupuncture. The trial ran from December 2012 to April 2015. Women were recruited in Berlin, Germany from December 2012 to August 2014 through posters and flyers at university campuses in Berlin, the intranet platforms of Charité—Universitätsmedizin Berlin and advertisements on two Berlin subway lines for 5 months.

Women in the intervention group were asked to apply acupuncture 5 days before the start of menstruation (1–2 times a day, 6 min per session) and on the days of pain (up to 6 times a day). On completion of the study, the

acupuncture features were activated on the app for the women in the control group and those interested could receive a personal introduction at the Institute for Social Medicine, Epidemiology and Health Economics, Charité—Universitätsmedizin.

To increase participation rates, the study group decided after 8 months to introduce a financial compensation of €30 and to change the upper age limit for participants from 25 to 34 years. We announced the introduction of the financial compensation, including the amount, on the advertisements for the AKUD study. On the more detailed AKUD information leaflet, we added that after successful study participation, participants would receive a compensation of €30. Trial participants who had completed all questionnaires were informed by email that they could collect their €30 at the Institute (later on in the trial, the money was transferred to participants' bank accounts). Women who participated in AKUD before the financial compensation was introduced received the information about the compensation at the latest on completion of the study.

As a result of these changes (financial compensation, change of age range), the monthly recruitment figures for AKUD almost doubled (mean  $n=13.4$  per month after the changes compared to mean  $n=7$  per month before). Women who were interested in participating in the study were invited to the Institute once for a screening and baseline visit (duration ~30–60 min). All other quantitative data were collected through the app with a time requirement of 5–10 min per cycle.

The aim of this qualitative study was to analyse women's motivations for participating in the trial, including whether the small financial compensation had an impact and to assess women's general views on financial incentives for research participation.

## **METHODS**

### **Design**

This qualitative study was nested in the AKUD trial,<sup>25</sup> and was conducted by the Institute for Social Medicine, Epidemiology and Health Economics at the Charité—Universitätsmedizin Berlin. Qualitative, semi-structured interviews were conducted with trial participants after they had completed all questionnaires for the AKUD trial, in order to avoid influencing the results of AKUD.

### **Sampling and recruitment**

Based on experience from other qualitative studies nested in randomised clinical trials, a sample size of 20–30 participants was aimed for.<sup>26–28</sup> Recruitment for the qualitative study took place between September 2013 and January 2015, with the selected participants invited for an interview by mail or phone. Up to March 2014, 26 women in the intervention group and 23 women in the control group were informed about the qualitative study; this led to 21 interviews up to March 2014. The sampling strategy was purposeful, with the sample

selected based on whether the women had been recruited to AKUD before or after financial compensation had been introduced. The aim was to interview more women (a minimum of 15) who had been recruited prior to the introduction of the incentive, as we assumed that their reasons would be more diverse and would differ from those who participated after the introduction of the incentive, for whom we assumed the financial incentive had played an important role.

In addition to the two groups 'non-incentive' and 'incentive', for our sampling strategy we further distinguished the women according to whether they had been randomised to the intervention group or to the waiting list (control group). We aimed for an equal distribution across the intervention and control groups for the interview sample.

Participants were invited to the qualitative study until we had conducted 21 interviews. Those who were not interested in an interview (~24 women) mentioned time constraints and no interest as reasons. We then analysed the materials and resumed recruitment in March 2015, adding another four interviewees to the sample to verify the findings of the analysis and ensure data saturation.

### Data collection

The first 21 interviews took place at the Institute, while the final 4 interviews were conducted by phone. All interviews were conducted only after written informed consent had been provided by interviewees.

The interviews were semi-structured according to an interview guide that had been developed based on the research question, existing literature and discussion within the study team (box 1). Additionally, sociodemographic information, pain intensity and medication use were collected for all interviewees.

All interviews were conducted one-to-one by SB. All authors are experienced qualitative researchers. SB received training in qualitative interviewing from CH and initial interviews were discussed by the research team and in a qualitative research group at the Charité - Universitätsmedizin Berlin with regard to interview techniques and improvements in the interview guide. SB was also responsible for the overall organisation of the AKUD trial but had no contact with study participants and therefore did not know the interviewees beforehand.

### Analysis

After each interview, the interviewer wrote an interview summary form<sup>29</sup> that included interpersonal aspects of the interviews as well as brief summaries for each research question based on interviewees' statements. These interview summary forms were included in the analysis to account for the relationship between the interviewer and interviewee in data analysis.<sup>29</sup> The interviews were digitally recorded and transcribed verbatim. Transcripts were pseudonymised by changing the women's names. Transcripts were uploaded into the

### Box 1 Interview guide

You have participated in the acupressure for dysmenorrhoea (AKUD) trial, which investigated the effectiveness of acupressure against menstrual pain.

#### Motivation for participation

What reasons did you have to participate?

Was the app a reason to participate?

Was the €30 a reason to participate?

#### Decision-making

How did you decide to participate?

Where did you hear about the study?

With whom, if anyone, have you discussed your study participation?

Have you participated in other studies? If so, what was your experience?

Do you have prior experience with acupressure or other complementary therapies? If so, what was your experience?

#### Menstrual pain

How have you dealt with menstrual pain prior to the AKUD study?

How have you experienced menstrual pain in your daily life?

#### Opinion incentive

What is your view on payment of research participants?

software program MAXQDA (V.11 for Mac) and a thematic analysis of the transcripts was conducted.<sup>30</sup>

All interview material was coded by SB. The first round of coding was done based on the interview guide. After this initial coding process to structure the data, each coded segment was analysed for present themes and coded accordingly. These two rounds of coding were conducted by SB for the first five interviews. The resulting themes and the coding tree were discussed by SB and CH and in a qualitative research group at the Charité - Universitätsmedizin Berlin to ensure intersubjectivity and grounding in the analysis. The coding process then continued for the first 21 interviews. In this process, major themes emerged that were discussed by the research team. All analysis steps were documented in written memos. After 21 interviews, analysis was considered complete as the same important themes continued to occur. Results were presented and discussed by the research team. To verify the findings of the analysis, four additional interviews were conducted, which presented the same themes and thus data collection was terminated.

## RESULTS

### Sample

Twenty-five women were interviewed (duration 10–50 min, mean 27 min), of whom 15 had been recruited to AKUD without financial incentive and 10 with financial incentive (table 1). The mean age of the women in the non-incentive group was 22.7 years (range 21–25) and in the incentive group 26.4 years (range 24–33). The interviewees were mostly highly educated and one-third mentioned having a medical background (eg, medical student or working at the Charité—



**Table 1** Characteristics of the interviewees

|  | Recruitment without incentive<br>n=15 |                 | Recruitment with incentive<br>n=10 |                |
|--|---------------------------------------|-----------------|------------------------------------|----------------|
|  | Intervention<br>n=4                   | Control<br>n=11 | Intervention<br>n=9                | Control<br>n=1 |
| Mean age (M, SD)   | 23.3±2.1                              | 22.6±2.0        | 26.6±2.8                           | 25             |
| ≥12 years of school education                                  | 3                                     | 11              | 9                                  | 1              |
| Painkiller or hormonal contraceptive against menstruation pain | 4                                     | 9               | 6                                  | 1              |
| Mean pain intensity during last menstruation (NRS*: mean, SD)  | 5.0±2.2                               | 5.3±1.7         | 5.8±1.6                            | 7.0            |
| Worst pain during last menstruation (NRS: M, SD)               | 7.5±1.0                               | 7.0±1.3         | 6.9±0.9                            | 8.0            |

\*Numeric Rating Scale.

Universitätsmedizin Berlin). The majority (n=19) of interviewees took painkillers for their menstrual pain, with ibuprofen, aspirin and paracetamol being the most common.

### Thematic findings

Analysis of the interviews showed that in order to understand women's participation in the AKUD trial, an understanding of their prior situation was important; namely, they all routinely experienced a significant impact of menstrual pain on their lives. The women had a history of searching for an appropriate solution and were unsatisfied with the limited options offered to them by their healthcare providers, namely painkillers or the contraceptive pill. While interviewees were open to painkillers, they were uneasy about taking them on a monthly basis. Interviewees had an understanding that randomised clinical trials are a necessary prerequisite to introducing a new treatment option into medical care. The financial compensation received was seen as a nice and appropriate bonus to their AKUD participation. We describe below the aforementioned themes in detail. While analysis was conducted separately for the incentive and non-incentive groups, results were similar. The findings are thus presented jointly, except with regard to financial compensation.

### Women's situation prior to trial participation

All women described how menstruation pain impacted their daily lives and disturbed their normal routines. For some, taking analgesics or the oral contraceptives alleviated the pain enough to allow their activities to continue. Others discussed how the pain affected everything—their social life, education, work—and was all-encompassing while it endured; some had to stay in bed and avoid all activities outside the house. Many interviewees described increased pain in stress situations and thus actively tried to reduce stress during menstruation. Such coping strategies became problematic when menstruation coincided with appointments that could not be postponed, while cancellation of appointments and work absences caused additional emotional stress

for some women. Sometimes, the pain also ruined key planned events.

Yes, right, (...) menstrual pain is just stupid, it messes up everything. It always comes when you have a birthday, or Christmas or when something is...nice actually, and then it's always so annoying when...you just lie in bed the whole time, or have to take a whole lot of painkillers (Berta, non-incentive, intervention group).

All interviewed women, except for three, regularly took analgesics to reduce their regular menstrual pain. However, all continued to search for more satisfying care. For example, of those who did not take analgesics at all, two dealt with their pain by lying down with a hot water bottle, while the third took contraceptive pills specifically to reduce her menstrual pain. For some interviewees, although they took analgesics and oral contraceptives, these medications were not effective in reducing their pain or they had not tolerated the medication (n=4 non-incentive; n=4 incentive).

None of the interviewees were against medication in general, though they did perceive it critically due to the potential side effects. They also did not generally think that complementary medicine is better than usual medicine. Nevertheless, they shared a critical view on analgesics as a regular solution for menstrual pain. The regularity and continuity of menstruation and the related pain, as mentioned by five women (n=2 non-incentive; n=3 incentive), made it difficult to accept analgesia as an appropriate solution.

So for me perhaps already the primary decisive reason was...because I thought maybe it helps somehow. And because it always bothered me that I have to take so many painkillers. If once a month you always have to take so many painkillers...actually I do not like the feeling (Viola, incentive, intervention group).

Many of the participants had sought alternatives to analgesics—including household remedies such as hot water bottles and tea—but with limited success. Some participants had tried, with mostly minimal effect, acupuncture, herbs, homeopathy, dancing/movement and

gymnastics. Such experiences left the women feeling alone with their symptoms and disillusioned with the medical system that had too few options for treating menstrual pain.

### Deciding on the AKUD trial

#### Hope for relief with no added risk

The AKUD trial was seen as a possible solution for their pain. The main reason for all interviewees for participation was to find a new or additional means to deal with their monthly ordeal.

So it's as I said. I'm sick once a month and I find that quite a limitation given the fact that it's [menstrual pain] not a disease. ... And I just hoped that something could help. That I could just ... cope with my everyday life. ... Because up to now there has been no solution (Zara, incentive, intervention group).

For many interviewees, it was important that the AKUD trial offered a non-drug therapy as a treatment option. As a reason for participation, the interviewees stressed the fact that they considered acupressure to be natural and thus could do no harm, more than they cited the potential effectiveness that acupuncture may have. Therefore, most of them had decided on participation spontaneously while reading about the trial on posters at locations such as the Charité - Universitätsmedizin Berlin or on official advertisement bulletins in the subway system. They did not talk to friends, family or physicians before making the decision. Questions they may have had such as time commitment were asked when they contacted the AKUD study center.

#### Adding a treatment option to medical care

In addition to finding relief for their own monthly pain, some interviewees clearly indicated that their participation could benefit other women, as a positive evaluation of acupressure would lead to more treatment options that physicians could offer patients. Such ideas were coupled with their belief that menstrual pain and dissatisfaction with current therapeutic options are an experience shared by many.

Women considered their study participation an important part of building evidence for medical practice. They were also open to the procedure of randomisation as a means to obtain valuable scientific evidence. Interviewees likewise emphasised the importance of informing gynaecologists of the results of the study, in the hope of reaching as many women as possible.

Exactly, I also wish that it, acupressure, somehow turns out to be a big success, and that it might be a real option....So for me the study proved really meaningful and you could say...okay, women have...such and such a percentage somehow to thereby have an improvement or so....And then you could, maybe you can actually publish that and can say, okay...try this...(Mia, non-incentive, control group).

### App as a motivational technology

Interviewees found the app useful and convenient; however, none considered it a reason for participation.

SB: And the app? Was that a motivation to take part in the study?

Dora: Um, well a motivation, I don't know, but I, it was very convenient in any case (non-incentive, control group).

### Financial benefit

Although financial gain could not have been a motivation for participation for the 15 women in the non-incentive group, all of the women in both groups expressed gratitude for the financial compensation. The majority agreed that financial compensation to cover transportation and time expenditure is appropriate for the efforts of trial participation. Only two women in the non-incentive group argued that the potential personal benefit outweighed any time expenditure and found financial compensation unnecessary.

Yes exactly. I see no reason, actually, no reason, uh, that you pay us for it [participation]....Because...uh, the people who participate gladly take the time for it and...are not forced into it, so...I don't know. For me it goes without saying that when there is actually no money, that it is not about money. Because, uh, you give us something. So we, we give our time, but we usually get a positive result, so ... (Olga, non-incentive, control group).

Some women in the incentive group did argue that financial compensation had been a deciding factor for participation (n=2). The majority of interviewees were students or in vocational training, and they mentioned the importance of a small subsidy to cover daily expenses.

Thea: Um...on the other hand, even if, if it's not much money, it's just still the thirty Euros that we as trainees, we're just...always at the limit anyway. Yes, still not a lot of money and then doing it also for thirty Euros is also...a trifle.

SB: Hmm, hmm. That was, so that was also something extra, it was an added incentive.

Thea: Yes (incentive, intervention group).

Overall, interviewees believed that clinical trials are necessary to improve medical practice. Thus, payment to incentivise recruitment is also necessary, since without it medical progress could be endangered.

Interviewees did not agree that compensation would impair their judgement regarding a trial's risks and benefits. They also argued that adults are capable of making a judgement of the risks involved and deciding independently what they are willing to undertake for a financial incentive. In addition, they agreed that the higher the risk of a trial, the higher the compensation should be. A few women mentioned that payment should not

exceed compensation for travel costs and time, and should not be the only reason for participation.

Yes, so I don't know if one can say that very poor people are forced to take part in some studies. That is, actually I find this not quite a correct statement, because I think there is no one who tells people you have to participate in this study. So I think it's always an individual decision that everyone can decide for himself whether he wants to join a study or not (Ana, non-incentive, control group).

Hmm. But I think that...it would be difficult to find participants at all....I think that's always the problem....It's just always the question of how necessary it is...to do this study....So I'm thinking: you must then weigh up, is it now really...worth it, that it might also save people from harm, ...or uh, does it not have to be? But I think that since the pharmaceutical industry also puts a lot of money into such studies, they could also do it [offer financial compensation] (Viola, incentive, intervention group).

## DISCUSSION

In this study, we show that the alignment of a range of factors and the characteristics of AKUD—offering a desired-for intervention, dealing with menstrual pain and that the intervention was viewed as harmless—were decisive for trial participation. In particular, the trial addressed a condition of importance to the women—that is, a monthly ordeal for which the medical system provides treatment options with which the women were uneasy, and for which they hoped to add another therapeutic option through their trial participation. It is also interesting that contrary to other studies that have shown that trust in physicians and good experience with the healthcare system may be reasons for volunteering in research,<sup>24 31</sup> the women in our study were dissatisfied with the medical care for their menstrual pain, which led them to participate in AKUD.

One may argue that, similar to other studies,<sup>21 24 31</sup> the women in our study participated in AKUD to achieve benefits both for themselves and for others. The women articulated personal benefits from participation as a motivation, but were clear that they also saw benefits of trial participation beyond themselves. The women had a clear expectation that if the trial results were positive, their participation would mean that women with menstrual pain would receive the new treatment option through their physicians. Thus, they had a clear understanding that medical practice is based on clinical trials and they expected clinical trial results to be translated directly into medical practice. Unlike some other studies,<sup>17 19</sup> none raised ideas of moral duty for participation.

As McCann has argued, for actual participation personal benefit is necessary, even though benefit for others is a reason to consider participation. This she calls 'conditional altruism'.<sup>23</sup> In this context, one may discuss financial compensation. Paying participants increases trial participation.<sup>7 15–17</sup> However, it is controversial as it may impede the idea of volunteerism,<sup>14 16</sup>

and also stands in contrast to the idea of participation as a moral duty.<sup>19</sup> The few studies conducted on research participants' views on financial compensation have mostly focused on healthy volunteers in phase 1 trials.<sup>14–17</sup> Although the women in our trial considered themselves healthy, their situation was quite different from phase 1 volunteers. Healthy volunteers in general are exposed to risk and discomfort, receiving in exchange money or access to healthcare otherwise unavailable.<sup>14 17</sup> Contrary to phase 1 trials, AKUD was a low risk trial offering an unknown but promising therapeutic option for a condition with a high impact on daily life. Some have argued that in phase 1 trials, risks are downplayed and financial compensation may affect autonomy and informed consent.<sup>14 16</sup> Indeed, women in our study argued that while compensation for trial participation is appropriate, it should not be a wage. However, interviewees were clear that research participants are autonomous individuals with the ability to make informed decisions and to assess the potential risks and benefits for themselves, also when there is financial compensation.

Furthermore, while some respondents mentioned that financial compensation was important for them in deciding on trial participation, it was not given by any as the deciding factor. Taking into consideration the suggestion of other authors that financial motivation may not initially be mentioned because it is not perceived as socially acceptable,<sup>32</sup> the fact that the women in the incentive group were older compared to those in the non-incentive group nevertheless clearly suggests that the recruitment rate for AKUD accelerated due to the increase in the age limit.

Another point that may have been of importance in the AKUD trial was the condition in question, namely menstrual pain. Menstrual pain is difficult to categorise in the usual terms of 'sick' and 'healthy'. Menstruation is considered 'natural' and 'normal',<sup>33</sup> but at the same time some women experience severe menstrual pain or other unpleasant symptoms. For instance, women in our study reported the need to limit their activities and reduce stress during menstruation, which impacted their daily lives and could lead to occupational impairment.<sup>34–36</sup> For this ambivalent state, there exist no culturally recognised strategies for menstruating women outside of biomedicine and the existing biomedical options were, for the women in our study, either ineffective or undesirable. This ambivalent state<sup>37</sup> may be an important reason why self-care approaches, such as the one tested in AKUD, may be seen as a better option than painkillers, as they are also considered 'natural'.<sup>34</sup>

Regarding the limitations of our study, it should be mentioned that our study sample was highly educated, and one-third of interviewees mentioned having a medical background. Furthermore, women who are satisfied with the solutions offered by the medical system for menstrual pain, mainly painkillers and oral contraceptives, had no reason to participate in the AKUD trial.

This sampling bias is reflected in the small number of women ( $n=7$ ; 28%) in our sample taking oral contraceptives, compared to women aged 18–29 years in the general population, of whom 72% take oral contraceptives.<sup>38</sup> The presented results must therefore be interpreted with this in mind.

Our results contribute to the ongoing discussion of whether financial compensation of research participants creates a risk of undue inducement. The women in our study considered themselves and others capable of adequately assessing risks and benefits and thus of making legitimately independent and voluntary choices. The women were clear that while financial compensation might have an impact on their decision-making process, it would not affect their judgement about risk. Finally, we suggest that the importance of clinical trials providing new treatments that could change medical practice might be an overlooked motivation for trial participation that needs to be addressed in future recruitment strategies.

### Implication for practice

Our study findings indicate that recruitment strategies should address the issue of the translation of study results into clinical practice and the potentials and pitfalls for shaping clinical practice through trial participation. A further point to address might be dissatisfaction with available treatment options, especially in case of 'normal' conditions that have an impact on daily life and for which biomedical treatments may not be the first or preferred choice for those affected, although they might nevertheless ask their medical providers for help. Opening up medical care for integrative approaches for such conditions should be considered.

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